

# SAFETY ACTION NOTICE

By arrangement with the Scottish Executive Health Department



## **BAXTER COLLEAGUE 1 AND 3 VOLUMETRIC INFUSION PUMPS: MALFUNCTION OF ON/OFF CIRCUITRY DUE TO FLUID INGRESS**

**SAN(SC)02/08**

**09 APR 2002**

**Medical Devices**

**Page 1 of 6 Pages**

### **SUMMARY**

Baxter Colleague 1 and 3 volumetric infusion pumps may “power on” or “power off” without the user operating the controls and without any alert or alarm. Advice is given on corrective measures and ongoing precautions.

### **BACKGROUND**

1. Baxter Healthcare Ltd have established that fluid ingress into the main body of Colleague volumetric infusion pumps can cause a short circuit leading to a malfunction of the on/off circuitry. The problem affects Colleague 1 single channel pumps (product codes FKM8151 and 2M8151K) and Colleague 3 triple channel pumps (product code 2M8153K). The malfunction may result in the pump spontaneously turning itself on or off, or rapidly cycling between on and off. This may occur without any alerts or alarms if the Panel Lockout facility is not enabled.
2. Fluid may enter the main pump body if the recommended cleaning instructions are not followed or if a significant quantity of IV solution should spill onto the pump. Fluids penetrating the pump may settle on the ribbon cable behind the keypad. Prolonged exposure may cause the ribbon cable to degrade and experience an intermittent short circuit, causing the behaviour described above.
3. Baxter Healthcare issued an Urgent Device Correction letter on 4 February 2002 (attached). The letter informed customers of the problem and provided details of the corrective measures required (fitting an insulator). The letter also outlined interim measures to be taken until the insulator is fitted as well as Cleaning Instructions to be posted in all pump cleaning areas.
4. Baxter service engineers and technical staff will fit the insulators to pumps on a “next seen” basis. Baxter has also arranged to provide insulators and installation instructions (Colleague Pumps Service Bulletin) on a no-cost basis where self-fit by a suitably qualified person is preferred.

### **ACTION**

5. This notice should be brought to the attention of all appropriate managers and staff.
6. Staff should be made aware of the attached Urgent Device Correction letter from Baxter Healthcare Ltd in connection with Colleague 1 and 3 volumetric infusion pumps.

<i>Suggested Distribution</i>	Accident & Emergency	Community Care	Device Managers
District Nursing	General Medical Practitioners	Health Centres	Hospices
Intensive Therapy Units	Maternity	Medical	Nursing
O.D.A.s	Oncology	Operating Departments	Radiotherapy
Risk Management	Safety Officers	Social Services	Wards



**SCOTTISH HEALTHCARE SUPPLIES**

Gyle Square Edinburgh EH12 9EB

A Division of the National Service Scotland for NHSScotland

*This notice was obtained from the INCIDENT REPORTING & INVESTIGATION CENTRE (public) website*

[http://www.nhsscotland.com/shs/hazards\\_safety/adverse\\_p.html](http://www.nhsscotland.com/shs/hazards_safety/adverse_p.html)

FAX: 0131 314 0722

E-MAIL: [iric@shs.csa.scot.nhs.uk](mailto:iric@shs.csa.scot.nhs.uk)

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### **CORRECTIVE MEASURES**

7. Baxter Colleague 1 and 3 volumetric infusion pumps with the following product code numbers should be identified: FKM8151, 2M8151K and 2M8153K.
8. Pumps which show an unexpected "power on", "power off" or similar anomalies should be removed from service and Baxter Technical Service should be contacted for further advice.
9. An insulator should be installed in the area of the ribbon cable during the next service activity on the pump as described Baxter's Colleague Pumps Service Bulletin, "Keypad Flex Connector Insulator Installation".

### **ONGOING PRECAUTIONS**

10. Cleaning fluid should not be sprayed onto the body of the pump nor should the pump be submerged for cleaning.
11. The pump cleaning instructions in the Baxter letter should be displayed in the pump cleaning area and should be followed.
12. The panel lockout feature as described in the User Manual should be used during infusions.

### **ENQUIRIES**

Enquiries to the manufacturer should be addressed to:

#### General Enquiries

Ms Fiona Taylor  
Baxter Infusion Systems Product Manager  
Baxter Healthcare Ltd  
Caxton Way  
Thetford  
Norfolk  
IP24 3SE

Tel: 01842 767000  
Fax: 01842 767099

#### Technical Enquiries

Reports of malfunction and requests for upgrading work, or parts & installation instructions, should be directed to:

Baxter Technical Service

Tel: 01604 704555  
Fax: 01842 704590



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**URGENT  
DEVICE  
CORRECTION**

4<sup>th</sup> February 2002

Re: **Colleague Volumetric Infusion Pump**

**Product Codes:** FKM8151, 2M8151K, HNM8151, DNM8151, GNM8151, CNM8151, WNM8151, PNM8151, 2M8151, 2M8153K, HNM8153, DNM8153, GNM8153, CNM8153, WNM8153, PNM8153, 2M8153.

Dear Customer,

Baxter has recently completed an investigation into reports of an infrequently occurring malfunction of the on/off circuit in the **Colleague 1 & 3 Volumetric Infusion Pump**. We are sending you this information so that you will understand the cause, the possible consequences, how to prevent it, and what Baxter will be doing to correct it.

A malfunction of the on/off circuitry can occur if fluid enters the main body of the pump and, after long-term exposure, causes a short circuit. A short circuit may then cause an unexpected “power on” or “power off” without a key press. Most commonly when the circuit shorts, a rapid power on/off cycling occurs. These events may occur with or without an alert or alarm and if they should occur during patient use, there is a potential that delivery of therapy may be interrupted.

Fluid may enter the main pump body if the recommended cleaning instructions are not followed or if a significant IV solution spill into the pump occurs. Fluids entering the pump may settle on the ribbon cable behind the keypad. Over prolonged exposure, the ribbon cable may degrade and experience an intermittent short circuit causing the behaviour described above.

During the next service activity on your pump, an insulator should be placed in the area of the ribbon cable to prevent the effect of any fluid contact on this circuitry. This activity should take no more than 5 minutes to complete. In the interim, any of the following actions will prevent this malfunction from occurring:

- Do not spray cleaning fluid onto the body of the pump or submerge the pump for cleaning. Please remember that the Colleague Volumetric Infusion Pump is not watertight. **Under normal use and following the recommended cleaning instructions (attached), cleaning fluid will not enter the pump and the behaviour described above will not occur.**
- As recommended in the Colleague User Manual, use the panel lockout feature as a standard procedure during infusions. Pressing the black Panel Lockout button on the back of the pump will enable this feature. When the Panel Lockout is enabled, all inputs from the on/off key are ignored and the behaviour described above should not occur or should it occur, a failure alarm will sound. Alternatively, the Autolock feature can be enabled in the configuration for each personality. This results in the automatic setting of the Panel Lockout 2 minutes after the start of an infusion.
- Install a protective insulator at the location of the ribbon cable. This insulator and the installation instructions will be provided to you at no charge by calling Baxter Technical Service on 01604 704555. If any of your pumps become exposed to excessive fluid from spills or inadvertent immersion, please remove the pump from service and contact Baxter Technical Service on the above number for advice.
- Remove from service any Colleague pumps in your inventory that are reported to show this on/off or similar behaviour and contact Baxter Technical Service on the above number for advice.
- Any pumps returned to Baxter, or seen by a Baxter Engineer, will have the insulator fitted on a next seen basis.

Please do not hesitate to contact your Baxter Infusion Systems Product Manager Fiona Taylor on 01635 206411 with any questions. The Medical Devices Agency has been notified of this action.

***In order to avoid receiving a repeat mailing of this letter, please complete the attached reply record and return it by FAX to the numbers listed on the reply record.***

We sincerely apologise for the inconvenience that this situation causes to you and your staff. Thank you for your assistance.

Sincerely,

Patricia Dargan  
Regulatory QA(d) Associate  
Baxter Healthcare

## **Colleague Volumetric Infusion Pump Cleaning Instructions**

Please post in all pump cleaning areas.

Prior to cleaning the pump, read this procedure carefully. Follow this procedure to ensure that the pump is not damaged during cleaning and remains under Baxter warranty. Contact your authorised Baxter Service Centre for further information.

### **CAUTIONS**

- **Do not use hard instruments for cleaning.**
- **Do not spray liquids or foam directly on the pump.**
- **Do not submerge the pump into liquids of any kind.**
- **Do not clean, disinfect, or sterilise any part of the pump by autoclaving or with the use of ethylene oxide gas. Doing so may damage the pump and void the warranty. Only external parts of the pump should be disinfected.**
- **Do not use the following chemicals on the pump, as they will damage the front panel: acetaldehyde, acetone, ammonia, benzene, hydroxytoluene, methylene chloride, or ozone. Do not use cleaners containing n-alkyl dimethyl ethyl benzyl ammonium chloride.**

### **Cleaning the Exterior**

Clean the pump after each use with soapy water, a solution of 10% bleach and water, isopropyl alcohol (up to 95%), or a commercial cleaning solution that does not contain any of the ingredients listed above. Follow the manufacturer's dilution instructions for concentrated cleaners. Clean the exterior using a soft cloth sparingly dampened, **not soaked**, with cleaning solution. To clean pumps that have been in an isolation area, select a cleaner that cleans and disinfects.

**Colleague Infusion Pump**  
**4<sup>th</sup> February 2002 Letter**  
**Reply Record**

Please complete and return this record to the FAX number listed below.

**01842 767134**

Reply Record

Completed By:

*(please print name)*

\_\_\_\_\_

Title:

*(please print)*

\_\_\_\_\_

Telephone Number:

\_\_\_\_\_

**Signature/Date:**

**REQUIRED FIELD**

\_\_\_\_\_

Facility Name and Address:

\_\_\_\_\_

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